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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/287,248 04/07/99 MCDEVITT

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EXAMINER

MCCAA, T

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

05/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.

09/287,248

Applicant(s)

MCDEVITT ET AL.

Examiner

Terri L Ivory - McCaa

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1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 August 1999.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-69, 115, 135 and 136 is/are pending in the application.
- 4a) Of the above claim(s) 115, 135 and 136 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-69, 115, 135, 136 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-69, drawn to a system for detecting an analyte in a fluid, classified in class 356, subclass 73.
  - II. Claims 115&135, drawn to a method for forming a sensor array , classified in class 435, subclass 283.1.
  - III. Claim 136, drawn to a method of sensing an analyte in a fluid, classified in class 436, subclass 536.
2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make different product such as an organizer for hair accessories or toys for travel.
3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product by using the product as a holder for accessories or paper weight.

4. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods. Group II is a method of making a sensor array while group III is a method of using the sensor array for sensing analytes in a fluid. The inventions have different modes of operation, different function and different effects therefore group II and III are patentably distinct.

5. Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Eric Meyertons on March 29 2001 a provisional election was made with traverse to prosecute the invention of group I, claims 1-69. Affirmation of this election must be made by applicant in replying to this Office action. Claims 115,135&136 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Drawings***

8. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

### ***Specification***

9. The disclosure is objected to because of the following informalities: page 38 line 22 has an open parenthesis after "K(off) )". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

11. Specification page 39 lines 14-30 disclose methods for detecting phosphate functional groups and the presence of bacteria by utilizing specific receptors. The specification does not disclose a method in which a particle produces a signal in the presence of the analyte, for instance, a particle that produces a signal in the presence of phosphate functional groups. It is not clear as to how any known particle is capable of generating a signal in the presence of any specific analyte with out some type of recognition component, i.e. a receptor, and a signal generating component, i.e. fluorescence. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

***Claim Rejections - 35 USC § 112***

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claims 1,12,37,38,40,42,43&69, the recitation "configured" is not clear as to what is encompassed by this term in each of the claims.

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14. Claim 17 is vague and indefinite. It is not clear as to what a semiconductor based photodetector may be. Does this mean that the semiconductor is attached to the bottom of the apparatus or part of the apparatus, or does it mean that the component of the photodetector is a semiconductor?

15. Claims 1,6-9,12,41,45-47, the recitation "substantially" is not clear as to that is encompassed by this term in each of the claims.

16. Claims 29 and 60 are vague. The recitation of "associated" is not clear as to how the indicator is associated with the receptor. Is the indicator bound to the receptor? Is the indicator bound near the receptor?

***Claim Rejections - 35 USC § 102***

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

18. Claims 1-2,7,9,10,14-16,19,23,40-42,45,48,49,51,53,54,68,69 rejected under 35 U.S.C. 102(a) as being anticipated by Lavigne et al (J. Am. Chem. Soc. 1998, 120,6429-6430).

Lavigne teaches a light source in which irradiates a series of polyethylene glycol – polystyrene resin beads through a cover plate ( Figure 1,C). The beads, comprising

indicator molecules selected for individual analytes, are confined individually on a micromachined well silicon/silicon nitride wafer in which the size of the well are formed to accommodate for the swelling of the bead when the bead is in contact with the analyte( Figure B). Absorption properties of the bead are detected by a CCD that was interfaced with the sensor array ( Figure 1C).

***Claim Rejections - 35 USC § 102***

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-9,11-16,18,19,39 are rejected under 35 U.S.C. 102(e) as being anticipated by Stabile et al U.S.Patent 5,872,623.

Stabile teaches a detection device comprising a light source which is reflected onto a clear lens above the sensor array. The light source is a light emitting diode ( Col.3, line 32&33) ( 101), a planar substrate support ( sensor array,105) comprising a top and bottom layer and cavities in which a particle or plurality of particles positioned in the cavity and are able to produce a signal or swell when the particle interacts with the analyte ( 121). The particle (s) may be between 100 and 200 um in diameter ( col. 15, Line 33-49). The support material may comprise glass, fused silica, silicon wafer or plastic. The glass, plastic or silicon are surface treated with a siliconizing agent which



minimizes the reactive sites that bind biological molecules. A detector, either a charge coupled device, photodiode array or a photodetector ( Col. 3, Lines 8-11), positioned beneath the apparatus for detecting the signal produced by the interaction of the analyte with the particle during use ( 112). Stabile also teaches a liquid distribution system that is coupled to the device in which delivers fluid from different reservoirs to the reaction cells or detection sites ( cavity) ( Col. 13 Line 58-67).

***Claim Rejections - 35 USC § 103***

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claim 17 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne in view of Kim U.S. Patent 5748091.

See discussion on Lavigne set forth above. Lavigne differs from the instant invention in failing to teach semiconductor photodetector.

Kim teaches an optical device comprising a semiconductor detector. The detector is utilized for the detection of ice on a sensor array ( Col2, Line 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate in the method of Lavigne a semiconductor photodetector as taught in Kim because the semiconductor photodetector is a

conventional type of detector, as shown by Kim, that may be utilized for the detection of electrical outputs on an array, such as the array in Lavigne.

22. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stabile in view of Ito et al (U.S.Patent 5,583,054).

See discussion on Stabile set forth above. This reference differs from the instant invention in failing to teach particles containing metal oxide.

Ito teaches reagent particles containing metal oxide as magnetic material. These particles provide the advantage of no residual magnetization ( Col. 4, Line 30). The reagent particles support immobilized antibodies on their surface (Col. 4, Lines 6-16)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Stabile by substituting particles containing metal oxide as taught in the method by Ito et al because metal oxide particles of Ito et al are known solid supports for supporting immunoreagent in assays for detection of analytes in a sample medium and thus an obvious alternative to the beads taught by Stabile. Stabile teaches using the beads for assays. The metal oxide particles of Ito et al would perform this function.

23. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stabile in view of Colin et al U.S.Patent 5,773,307 .

See discussion on Stabile set forth above. This reference differs from the instant invention in failing to teach metal particles.

Colin teaches a primary reagent, utilized in analyte detection, consisting of metal particles in a suspension consisting of at least one anti – ligand fixed to the surface of the particle ( col.2, Line 25-35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stabile by substituting metal particles as taught by Colin for the beads taught by Stabile because the metal particles of Colin can be utilized for immobilizing ligands for binding of reagents or analytes and thus an obvious alternative to the beads of Stabile. Stabile teaches using beads for assays. The metal particles of Colin would perform this function.

24. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stabile in view of Clark Jr. et al U.S.Patent 5,690,807.

See discussion on Stabile set forth above. This reference differs from the instant invention in failing to teach semiconductor particles.

Clark teaches a method for producing semiconductor particles. Particles ranging from 1-1000 nanometers are useful for their quantum confinement effects and their luminescent properties ( Col.1, Line 18-21).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Stabile by substituting semiconductor particles as taught in the method of Clark for the beads of Stabile because the semiconductor particles provide the advantage of quantum confinement and luminescent properties. The device of Stabile provides for optical measurements to

detect analytes. The luminescent properties of the semiconductor particles of Colin obviate the need for label reagents in assays to generate optical signals.

25. Claim 24 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne in view of McGarry et al U.S. Patent 5,248,742.

See discussion on Lavigne set forth above. This reference differs from the instant invention in failing to teach divinyl benzene as a crosslinking agent for the polymeric resin.

McGarry teaches various vinyl crosslinkers utilized in the formation of polymeric resins. Divinyl benzene is an example.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the polymeric resin in the device of Lavigne by adding a cross linker such as divinyl benzene as taught in the method of McGarry because polymeric resins are known in the art and addition of various substituents and cross linking agents such as divinyl benzene are conventional monomers used in the production of polymeric beads.

26. Claim 25 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne in view of Bretscher et al U.S. Patent 5,714,122.

See discussion on Lavigne set forth above. These references differ from the instant invention in failing to teach a receptor that produces a signal in response to pH in a fluid.

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Bretscher teaches pH sensitive optical indicators used in the detection of CO<sub>2</sub> in blood. The pH change can be monitored by fluorescence or absorption ( Col. 7, Line 56-66).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lavigne by incorporating a dye as taught in the device of Bretscher because the dye taught in Bretscher may be incorporated onto a particle as a receptor and utilized in the device of Lavigne to detect pH changes in a sample medium as a detection parameter that is to be detected. The analyte or parameter that is to be detected or <sup>monitored</sup> ~~maintained~~ dictates the reagents that are to be used. One of ordinary skill in the art would be motivated to use the dye of Bretscher in the device of Lavigne if the device of Lavigne is for the detection of pH changes.

27. Claim 27 and 58 rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne et al in view of Russel U.S. Patent 5,137,833.

See discussion on Lavigne set forth above. This reference differs from the instant invention in failing to teach receptors for carbohydrate analytes.

Russel teaches a class of dyes that exhibit quantitative sensitivity to the presence of certain polyhydroxyl compounds such as sugars. The dye is bound to a derivative of boronic acid, arsenious acid or germanic acid. The simplest detection system comprises a sample carrier, a light source or source of radiation and a detector capable of measuring the intensity of radiation passing through the sample ( Col.2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Lavigne by incorporating a receptor comprising a dye and a derivative of boronic acid as taught by Russel because on the beads of Lavigne because the analyte that is to be detected dictates the reagents that will be used. One of ordinary skill in the art would be motivated to use the dye reagents of Russel on the beads in Lavigne if the device of Lavigne is intended for the detection of carbohydrate analytes. Russell shows that the disclosed dye reagents can be used in optical apparatus such as the device of Lavigne.

28. Claims 28 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne in view of Schutz et al ( Biophysical Journal Vol. 74 May 1998).

See discussion on Schutz set forth above. This reference differs from the instant invention in failing to teach colocalization of indicators on a receptor.

Schutz teaches colocalization of two types of ligands on a receptor to be utilized in the in far – field video –rate fluorescent microscopy ( Page 2223). Observation of emission from an acceptor molecule during illumination of a donor allows to test for energy transfer ( Page 2225).

It would have been obvious to one of ordinary skill in the art to modify the invention of Lavigne by incorporating a receptor comprising colocalized ligands as taught in Schutz et al because this receptor may be incorporated onto a particle and provides the advantage of high sensitivity binding to analytes in a biological sample for detection in optical systems such as the device of Lavigne.

29. Claim 26 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne in view of Arnold et al U.S.Patent 5,616,790.

See discussion on Lavigne set forth above. Lavigne differs from the instant invention in failing to teach receptor producing a signal in the presence of a metal ion.

Arnold et al teaches a fluorescent metal-chelating amphiphile utilized as a sensor for the detection of metal ions in a solution. The disclosed amphiphile is placed in a lipid bilayer or other suitable matrix. The resulting mixed lipid bilayer system functions as a sensor for metal ions (col. 4, Line 1-41).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Lavigne by substituting the amphiphile of Arnold for the beads of Lavigne because the amphiphile of Arnold forms aggregates when placed in a lipid bulayer to function as the beads used by Lavigne to permit detection of metal ions in the device of Lavigne. The choice of analyte dictates the reagents that are required in the device of Lavigne. For the detection of metal ions in the device of Lavigne, one of ordinary skill in the art would be motivated to use the appropriate reagents for detection of metal ions.

30. Claim 29 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne in view of Issachar U.S.Patent 5,156,972.

See discussion on Lavigne set forth above. Lavigne differs from the instant invention in failing to teach an indicator associated with a receptor such that the

indicator is displaced from the receptor in the presence of an analyte to produce a signal.

Issachar teaches biosensors in which immobilized on a solid phase, receptors and ligands are connected together in the absents of the analyte, and in the presence of the analyte, the ligand is displaced from the receptor to produce a signal ( col.6, line 29-39).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Lavigne by incorporating a receptor - ligand moiety for signal detection of an analyte by displacement of the ligand from the receptor in the presence of the analyte as taught by Issachar because the Issachar shows it to be conventional in the art to perform displacement immunoassays in optical apparatus.

31. Claims 30,35,36,61,66,67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne in view of Fish et al U.S.Patent 5,126,276.

See discussion on Lavigne set forth above. These references differ from the instant invention in failing to teach different types of receptors.

Fish teaches that receptors are selectively attached onto supports and the type of receptors differ in respect to the analyte being assayed. Examples of receptors that may be used are antigen, antibody and nucleic acid (Col.7, Line 54-62).

It would have been obvious to one of ordinary skill to modify the invention of Lavigne by incorporating a receptor according to the analyte being assayed as taught in the method of Fish because specific receptors incorporated onto particles or solid



substrates are well known in the art for binding of specific and particular analytes of interest for detection purposes. The choice of reagents to be used in the device of Lavigne is dictated by the analyte that is to be detected.

32. Claims 31 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne in view of Lauritzen ( Electrophoresis 1993, 14,852-859).

See discussion on Lavigne set forth above. This reference differs from the instant invention in failing to teach a peptide receptor.

Lauritzen teaches a peptide receptor immobilized on a solid substrate for antibody binding.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lavigne by incorporating a peptide receptor as taught by Lauritzen because to provide for the detection of an antibody one would be motivated to use a reagent for detection of an antibody in the device of Lavigne. The choice of reagent to be used in the device of Lavigne is dictated by the analyte that is to be detected. Lavigne teaches reagents on the beads for detection of a specific analyte. The peptide receptor of Lauritzen can be immobilized on a solid support such as the beads of Lavigne to provide for the detection of antibodies on the device of Lavigne.

33. Claim 32 and 63 rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne in view of Khanna et al U.S.Patent 5,223,393.

See discussion on Lavigne set forth above. This reference differs from the instant invention in failing to teach an enzyme receptor.

Khanna teaches an enzyme immunoassay in which an enzyme receptor is utilized for analyte detection (Col. 2). The enzyme receptor may be immobilized on particles of beads ( Col.3, Lines 17-36). The enzyme receptor can be used to detect polypeptides, proteins, nucleic acids, polysaccharides etc. ( Col.4, Lines 46-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lavigne by incorporating an enzyme receptor as taught in the method of Khanna on the beads of Lavigne because Lavigne teaches providing reagents on the beads for detection of an analyte and Khanna shows it to be conventional in the art to provide an enzyme receptor on beads as a reagent for detection of a desired analyte.

34. Claim 33 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne in view of O'Daly et al U.S.Patent 5,391,272.

See discussion on Lavigne set forth above. This reference differs from the instant invention in failing to teach a synthetic receptor.

O'Daly teaches an example of a different type of binding entity such as a synthetic receptor to which a ligand or cross reacting compound binds( col.6, Line 39-44).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lavigne by incorporating an synthetic

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receptor as taught in the method of O'Daly because O'Daly shows it to be conventional to use synthetic receptors in solid phase immunoassays. Lavigne teaches using a reagent on the beads for detection of analyte and O'Daly teaches immobilizing a synthetic receptor on a solid phase ( which could be a bead) for detection of analyte.

35. Claim 34 and 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne in view of Cho et al ( Science Vol. 261 September 3, 1993).

See discussion on Lavigne set forth above. This reference differs from the instant invention in failing to teach unnatural biopolymer.

Cho teaches the synthesis of unnatural biopolymers composed of building blocks other than amino acids. These biopolymers are used as a screening tool for their ability to function as receptors for monoclonal antibodies (Page 1303).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lavigne by incorporating a unnatural biopolymer as a receptor as taught by Cho because the unnatural biopolymers are commercially available (page 1303) and represent a type of receptors that may be incorporated onto particles for binding of monoclonal antibodies for detection purposes. Lavigne teaches using a reagent on the beads for detection of analyte. One would be motivated to use the polymer of Cho et al on the beads of Lavigne to provide for the detection of monoclonal antibodies if monoclonal antibodies are the desired analyte. The choice of reagent is dictated by the desired analyte.

36. Claims 43, 44, 46, 47, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne in view of Stabile.

See discussion on Lavigne set forth above. Lavigne does not teach a top layer and a bottom layer of a device.

Stabile teaches a device in which the sensor array comprises a top and bottom layer wherein the bottom layer is positioned below a bottom surface of the supporting member, and where the top cover layer is positioned above the upper surface of the supporting member, and wherein the bottom and top layer are positioned such that the particle is contained within the cavity by the bottom and the top cover layer ( Figure1). The device also comprises a fluid delivery system coupled to the device ( Col. 13 Line 58-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lavigne by incorporating a device taught by Stabile because Stabile device comprises a top lens portion for even dispersal of light through the planar substrate comprising multiple detection sites and bottom portion for the detection of the light from the multiple detection sites of the planar substrate for signal evaluation of analytes.

### **Conclusion**

37. Claims 1-69 are not allowed.

38. The prior art made of record and not relied upon is considered pertinent to applicants disclosure.


- a. Cole et al USP 5550373
- b. Smith et al USP 4874499
- c. Wise et al USP 5262127
- d. Wise et al USP 5385709

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terri L Ivory - McCaa whose telephone number is 703-605-1207. The examiner can normally be reached on M-F 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Terri McCaa  
Patent Examiner  
Art Unit 1641  
May 3, 2001

  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800/691